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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,574	06/25/2003	James Roy Maxwell	1391/1558	6293
28455	7590	11/30/2005	EXAMINER	
WRIGLEY & DREYFUS 28455 BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			GRAFFEO, MICHEL	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/607,574	Applicant(s) MAXWELL ET AL.	
	Examiner Michel Graffeo	Art Unit 1614	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-45 and 47-70 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,3-45 and 47-70 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

Claims 1, 3-45 and 47-70 are pending and examined.

In response to the Office Action dated 26 July 2005, Applicant has amended claims 1, 3-20, 30-31, 35-36, 39, 41-45, 47-57 and 70, canceled claims 2 and 46 and provided arguments for the patentability of claims 1, 3-45 and 47-70.

In light of Applicant's Amendment dated 31 October 2005, the rejections to claims 3-8, 17-20, 30-31, 35-36, 43-45 and 47-49 under 35 USC §112 have been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al.

Cherukuri et al. teach a chewing gum composition and methods of making same comprising:

- cinnamic aldehyde (see col 7 lines 11-12) present in an amount of from 0.05 to 3% (see col 7 line 45),
- up to about 90% maltodextrin (see col 5 lines 35-40),
- up to about 30% fillers (see col 5 lines 26-31 and col 4 lines 57-59) such as wood (see col 4 line 35), calcium carbonate, magnesium silicate, tricalcium phosphate and dicalcium phosphate (see col 4 lines 64-66),
- hydrocolloids such as alginates (of which one skilled in the art would find sodium and calcium to be obvious species), starch, pectin, gum arabic (see col 8 lines 15-21) wherein the starch pectin and gum arabic can be present in amounts of 0.1 to 12% (see col 8 line 45) and carrageenan (see col 5 line 22),
- a medicament (see col 9 lines 55-end) such as aspirin, fluorides and calcium carbonate (see col 10 Lines 1-6), food acids such as citric, adipic and tartaric acid (see col 5 line 25),

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- softening agents (see col 5 line 15) such as propylene glycol present in amounts up to about 30% (see col 4 lines 45-63),
- an effective amount of a colorant (see col 5 line 3),
- flavoring agents (see col 6 line 59) such as oils (spearmint) and synthetic flavoring oils (see col 6 lines 65-end) or menthol (see col 7 line 8) present in an amount of from 0.05 to 3% (see col 7 lines 38-45), and,
- emulsifiers such as lecithin (see col 5 line 20).

Cherukuri et al. do not recited an edible film per se.

Pearce et al. teach an edible film comprising fillers, (see paragraph 41), hydrocolloids, (see paragraph 28), flavoring (see paragraph 57), color (see paragraph 133) and cinnamaldehyde (see paragraph 63).

Cherukuri et al. do not teach per se a method of delivering a certain amount of cinnamaldehyde to the oral cavity. Nonetheless, one skilled in the art would find it obvious to routinely optimize the amount of cinnamaldehyde that is added and subsequently released into the oral cavity. Cherukuri et al. expressly suggest that the amount of flavoring “employed is normally a matter of preference subject to such factors as flavor type, individual flavor, gum base and strength desired. Thus, the amount may be varied in order to obtain the result desired in the final product. Such variations are within the capabilities of those skilled in the art without the need for undue experimentation.”. (see col 7 lines 38-44).

Cherukuri et al. do not teach a method for reducing the number or activity of bacterial in the oral cavity per se. Nonetheless, Cherukuri et al. described a composition comprising the same ingredients as those in the instant claims, wherefore; the composition must have the same functional properties. Therefore, absent evidence to the contrary, use of the composition described in Cherukuri et al. necessarily reduces the number or activity of bacteria in the oral cavity.

One of skill in the art would be motivated to combine Cherukuri et al. with Pearce et al. and as combined would make obvious the invention as claimed above. Both references are directed to edible compositions and contain the same ingredients, all of which are well known in the art. One skilled in the art would find it obvious, given the same set of ingredients to make both a film and a gum as described above. Moreover, one will necessarily make the claimed composition by employing the ingredients claimed in the amounts claimed. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 6, 18, 36, 44-45 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above in view of US Patent Application No. 2003/0224090 to Pearce et al. as applied above and further in view of WO 99/18940 to Bush Boake Allen Inc.

Cherukuri et al. do not teach a composition comprising about 20-30% of a hydrocolloid; 6-25% cinnamaldehyde; 10-15% a flavoring agent; or heating the aqueous solution to a temperature of 40-60°C.

The WO 99/18940 reference teaches processed starches present in an amount up to about 60% (see page 17 line 31), flavoring agent/malodor counteractant such as cinnamic aldehydes (see page 1 lines 25-end) present in an amount of from 0.0001 to 10% (see page 9 lines 4-9), and a process wherein the aqueous mixture was heated preferably from about 40-70°C.

One skilled in the art would be motivated to combine WO 99/18940 with Cherukuri et al. and Pearce et al. WO 99/18940 is directed to an oral vehicle such as chewing gum comprising the traditional ingredients such as fillers (see page 15 lines 20-26), hydrocolloids (see page 17 line 32), maltodextrin and sweeteners (see page 17 line 32 as well). One skilled in the art would be motivated to use the process of making the oral vehicle as well as any variations of ingredients as described in WO 99/18940 because the ingredients are the same and traditional in the art. Moreover, one skilled in the art would expect success using the method described in WO 99/18940 particularly since the ingredients are the same. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above in view of US Patent

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Application No. 2003/0224090 to Pearce et al. as applied above and further in view of US Patent No. 5,487,902 to Andersen et al.

Cherukuri et al. do not disclose a composition comprising a medicament comprising zinc gluconate or triclosan for example. Andersen et al. teach a chewing gum comprising triclosan and zinc gluconate (see col 9 lines 29 and 39).

One of skill in the art would be motivated to combine Andersen et al. with Cherukuri et al. Both references are directed to chewing gums containing traditional ingredients. Moreover Cherukuri et al. teach that medicaments can be added to the composition and teach that the list provided is non-limiting (see col 9 lines 55-end and continuing in col 10 lines 1-6). One of skill in the art would find it obvious to combine the two chewing gum references and include the medicaments in Andersen et al. into the invention of Cherukuri et al. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

New Claim Rejections - 35 USC § 103

Claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 above in view of US Patent No. 5,433,960 to Meyer.

Cherukuri et al. do not recite an edible film per se.

Meyer teach an edible film comprising maltodextrin (see col 6 line 28), gums (see col 6 lines 30-35 and fillers (calcium phosphate fillers, see col 11 lines 55-end).

One of skill in the art would be motivated to combine Cherukuri et al. with Meyer and as combined would make obvious the invention as claimed above. Both references are directed to edible compositions containing maltodextrin, fillers and hydrocolloids as ingredients, all of which are well known in the art. One skilled in the art would find it obvious, given the same set of ingredients to make both a film and a gum as described above. Moreover, one will necessarily make the claimed composition by employing the ingredients claimed in the amounts claimed. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 6, 18, 36, 44-45 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 in view of US Patent No. 5,433,960 to Meyer as applied above to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 and further in view of WO 99/18940 to Bush Boake Allen Inc.

Cherukuri et al. do not teach a composition comprising about 20-30% of a hydrocolloid; 6-25% cinnamaldehyde; 10-15% a flavoring agent; or heating the aqueous solution to a temperature of 40-60°C.

The WO 99/18940 reference teaches processed starches present in an amount up to about 60% (see page 17 line 31), flavoring agent/malodor counteractant such as

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cinnamic aldehydes (see page 1 lines 25-end) present in an amount of from 0.0001 to 10% (see page 9 lines 4-9), and a process wherein the aqueous mixture was heated preferably from about 40-70°C.

One skilled in the art would be motivated to combine WO 99/18940 with Cherukuri et al. and Meyer. WO 99/18940 is directed to an oral vehicle such as chewing gum comprising the traditional ingredients such as fillers (see page 15 lines 20-26), hydrocolloids (see page 17 line 32), maltodextrin and sweeteners (see page 17 line 32 as well). One skilled in the art would be motivated to use the process of making the oral vehicle as well as any variations of ingredients as described in WO 99/18940 because the ingredients are the same and traditional in the art. Moreover, one skilled in the art would expect success using the method described in WO 99/18940 particularly since the ingredients are the same. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 in view of US Patent No. 5,433,960 to Meyer as applied above to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 and further in view of US Patent No. 5,487,902 to Andersen et al.

Cherukuri et al. do not disclose a composition comprising a medicament comprising zinc gluconate or triclosan for example. Andersen et al. teach a chewing gum comprising triclosan and zinc gluconate (see col 9 lines 29 and 39).

One of skill in the art would be motivated to combine Andersen et al. with Cherukuri et al. Both references are directed to chewing gums containing traditional ingredients. Moreover Cherukuri et al. teach that medicaments can be added to the composition and teach that the list provided is non-limiting (see col 9 lines 55-end and continuing in col 10 lines 1-6). One of skill in the art would find it obvious to combine the two chewing gum references and include the medicaments in Andersen et al. into the invention of Cherukuri et al. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 in view of US Patent No. 5,433,960 to Meyer as applied above to claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 and further in view of US Patent No. 3,452,138 to Granatek et al.

Cherukuri et al. do not disclose a composition comprising a medicament comprising urea with a particular example. Cherukuri et al. teach in col 10 line 2 that antacids can be included in the composition. Granatek et al. is cited to provide an example of an antacid containing urea (see Title).

Response to Arguments

Applicant's arguments filed 31 October 2005 have been fully considered but they are not persuasive.

Applicants argue that Cherukuri does not teach a method for reducing the number or activity of bacterial in the oral cavity. Applicant's argument notwithstanding, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present and the cinnamaldehyde must then necessarily function as an antibacterial agent. Additionally, Cherukuri does not recite pullulan as a necessary ingredient and therefore teaches edible products which do not contain pullulan.

Applicants contend that Pearce et al. do not properly benefit from the filing date of Provisional Application No. 60/368821. Examiner relies on Pearce for a teaching of an edible film having the same ingredients as Cherukuri (fillers, hydrocolloids, flavoring, color and cinnamaldehyde. But for the cinnamaldehyde, the '821 reference supports an edible film comprising color, gums and flavor (see page 2 of the '821 application – which incorporates US Patent No. 5,994,450 which teaches fillers and gums as well). Even absent a teaching of cinnamaldehyde in the priority documents of Pearce, Pearce remains a reference for what it teaches, notably an edible film comprising fillers, hydrocolloids, flavoring and coloring agents and can properly rely on the '821

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Application for a teaching of an edible film comprising fillers, hydrocolloids, flavoring and coloring agents.

Cherukuri teaches a method of making a chewing gum composition comprising a maltodextrin, a filler, a hydrocolloid and cinnamaldehyde. As combined with the Pearce and Meyers references, there is a teaching to one of ordinary skill in the art to make an edible film comprising maltodextrin, a filler, a hydrocolloid and cinnamaldehyde. Since the Cherukuri reference teaches the process for making a composition comprising the above ingredients and the Pearce and Meyers references teach the method of making an edible film, one of ordinary skill in the art would have been in the possession of making the edible film with the ingredients as claimed.

Applicant also state that the ingredients disclosed in Bush (WO 99/18940) are "not the same as those in the Applicant's invention" (see page 15 of Applicant's Response) but do not provide any additional support for the argument. Therefore, as highlighted in the prior Office Action and above, Bush teaches an oral vehicle comprising fillers, maltodextrin, hydrocolloids and sweeteners as recited in the instant claims.

As Applicant points out, US Patent No. 1,056,212 to Puetzer et al. is incorrect. Examiner uses a different reference, US Patent No. 3,452,138 to Granatek et al., to show the state of the art at the time the application was filed and therefore believes that no new ground of rejection is presented since the state of the art has remained the same.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28 November 2005

MG


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